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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/365,576	08/02/1999	DAVID MOORE	00786/246002	1944

21559 7590 10/06/2004

CLARK & ELBING LLP
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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/365,576	MOORE ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,10,13-16 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 10, 13-16, 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendment filed 8 September 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments have been fully considered but they are not found persuasive.

4. The Declaration of David Moore filed on 29 October 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the 35 USC 102(e) reference. The Declaration of Dr. Moore filed December 28, 2001 does not overcome the rejection because applicant did not provide showing under 37 CFR 1.6O8(b) See MPEP 2308.02.

Claim Rejections - 35 USC § 101

5. Claims 7, 10, 13-16 and 27-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility.

The reasons for the rejection has been set forth in the previous office action.

Applicants argue that the inhibitory action of RIP-15 on RXR would provide utility for diseases associated with RXR such as hyperthyroidism because thyroid hormone

receptor heterodimerizes with RXR. However, no evidence is provided that RIP-15 can inhibit thyroid hormone receptor in hyperthyroidism. Furthermore, no compounds which increase RIP-15 expression is taught in the specification. Applicants further argue that antibodies to RIP-15 can be used to detect or monitor RXR-related diseases. However, no evidence has been provided that RIP-15 antibodies can be used to detect hyperthyroidism. In fact the closest prior art of record, Liao et al., disclose and teach an orphan receptor whose function is not known at the time of the invention and no known diseases are taught associated with the receptor. The binding of the RIP-15 to RXR does not by default provide substantial utility because RIP-15 is an orphan receptor whose function is not known. RXR heterodimerizes with many proteins whose function is related to the specific protein it binds with. For example RXR binds RAR and thus diseases associated with RAR has utility. However, an orphan protein which binds RXR such as RIP-15 does not have nexus to RAR just because it binds RXR. The RXR does not provide nexus to the disease but the protein which binds RXR and RIP-15 is an orphan receptor whose function is not known and does not provide nexus to diseases merely based on interaction with RXR. In fact further experimentation is necessary to determine the function of RIP-15 and it's nexus to a disease.

6. Claims 7, 10, 13-16 and 27-32 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. Claims 7, 10, 13-14, 16, 27, 28 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Written description rejection.

Claims 7, 10, 13-14, 16, 27, 28 and 31-32 encompass a peptide variant because of recitation of percent identity. However, the specification only discloses working example of species of RIP-15 but do not disclose a working example of the genus of other amino acids. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. The essential feature of the invention is the RIP-15 of SEQ ID NO:3. No functional limitation can limit the structural limitation because the receptor is an orphan receptor.

8. Claims 7, 10, 13-16 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims encompass variant proteins because of the percent identity claim limitations. However, the specification fails to teach how to make and use all fragments, derivatives, and variants because the claimed proteins are orphan receptors without a known ligand. Changes in the ligand binding domain is unpredictable because without a ligand for the receptor, one skilled in the art at the time of the invention could not determine which amino acid changes to the ligand binding domain would be functional without a ligand to test the function. Furthermore, even in protein domains where function is known, it would require undue experimentation to determine the effect of unlimited mutations because functional domains of proteins require proper protein conformation and the prediction of protein conformation based on primary amino acid sequence is unpredictable (Bowie et al.(S)). Such determination requires empirical experimentation to determine the amino acids changes which are functional and non-functional. Thus, sequence similarity alone without function is insufficient to support claims to polypeptide other than the disclosed sequence where the genus includes inactive proteins. Without such guidance the experimentation necessary to make and use the variants, derivatives, and fragments is undue.

Applicants argue that it would be routine for one skilled in the art to determine the function for the orphan receptor RIP-15. However, one skilled in the art at the time of the invention did not know the function of the orphan receptor. In fact the closest prior art of record, Liao et al., disclose and teach an orphan receptor whose function is not known at the time of the invention and no known diseases are taught associated with the receptor. Furthermore, further empirical experimentation would require be required

to determine the function. It is not in a readily available form to use. The experimentations are circular arguments which in the end requires further experimentation where the end result cannot be predicted because the function of the receptor is not known and further experimentation is needed to determine the function.

Priority

9. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 7, 10, 13-14, 16, 27-32 of this application. See MPEP 706.02.Applicants argues that priority was claimed to parent application thus should be entitled to the priority. However, MPEP 706.02 states that claims which fail to provide adequate support under 35 USC 112 does not receive prioirity. The 35 USC 112 rejection has been set forth above.

Claim Rejections - 35 USC § 102

10. Claims 7, 10, 13-14, 16, 27, 28 and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Liao et al.(US 5,639,616).

The reason for the rejection has been set forth in the previous office action.

Applicants request a clarification of why Declaration of Dr. Moore does not overcome the rejection. MPEP 2308.02 states that applicant must provide showing under 37 CFR 1.608(b). The Declaration of Dr. Moore filed December 28, 2001 does

not overcome the rejection because applicant did not provide showing under 37 CFR 1.6O8(b). See MPEP 2308.02.

11. Claims 7, 10, 13-14, 16, 27, 28 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Liao et al.(US 5,639,616).

The reason for the rejection has been set forth in the previous office action.

Applicants argue that priority to parent application does not make the rejection a 102(b). However, the priority has been denied for the reasons set forth above.

12. No claims are allowed. SEQ ID NO: 3 is free of the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
30 September 2004